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EXAMINER

PHAM, HUNG Q

ART UNIT	PAPER NUMBER
2168	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,382

Applicant(s)

STOLOFF ET AL.

Examiner

HUNG Q. PHAM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10,15,16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Amendment to the Claims

The Claims filed on 07/19/06 contains claims 11-14 drawn to an invention nonelected without traverse in the Office Action 03/24/2005. Claims 12-14 have not provided with proper status identifiers. This error was discussed in the previous Action. Examiner respectfully request applicants to correct these claims with proper status identifier in the next communication.

Specification

Applicants' arguments with respect to the objection of the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

Claim Objections

The objection of claims 1 and 15 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112

The rejection of claims 1 and 15 under 35 U.S.C. § 112, second paragraph, has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 101

- The rejection of claim 8 under 35 U.S.C. § 101 has been withdrawn in view of the cancelation of claim 8.

- Applicants' arguments with respect to the rejection of claims 15, 16 and 18-21 under 35 U.S.C. § 101 have been fully considered but they are not persuasive.

Claim 15 has been amended with *processing means*. The claimed limitation *processing means* is software to *provide a web site having information about medical products*. Instead of defining the system by identifying the physical structure of the system as set forth in MPEP 2106 (IV)(B)(2)(a), the system as claimed direct to software per se. The rejection of claims 15, 16 and 18-21 under 35 U.S.C. § 101 is sustained.

Claim Rejections - 35 USC § 103

- Applicants' arguments with respect to the rejection of claims 1, 2, 4, 7, 8, 15, 16, 18 and 21 under 35 U.S.C. § 103 have been considered but are moot in view of the new ground(s) of rejection.

- Applicants' arguments with respect to the rejection of claims 9 and 10 under 35 U.S.C. § 103 have been fully considered but they are not persuasive.

As argued by applicants at pages 8 and 9:

Regarding the rejection of independent claim 9, the Examiner indicated that drugstore.com teaches the claimed "network accepting an electronic submission indicative of an unmet need for the medical products whereby unmet needs related to the medical products may be determined." Office action, pp. 9-10. Applicants respectfully disagree and submit that drugstore.com does not teach the claimed "accepting an electronic submission indicative of an unmet need for the medical products whereby unmet needs related to the medical products may be determined" as noted above with respect to claims 1 and 15. The pages of drugstore.com web site relied upon in the Official Action are <http://web.archive.org/web/20000310162140/www.drugstore.com/pharmacy/ayp/ask.asp> ("page 3") and <http://web.archive.org/web/20000208084226/www.drugstore.com/pharmacy/ayp/default.asp?Teare=2113> ("page 4"). Page 3 of the drugstore.com web site allows a user who needs "quick, private information" about the user's "health or medications" to ask a question by typing the question in the

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"Your question:" box, providing requested information, and clicking on the "Submit Question" button. Page 4 of the drugstore.com web site has been described previously. However, while drugstore.com teaches accepting submissions of a question related to the user's health or medications, it is not the same as accepting a submission indicative of an unmet need for the medical products, as claimed by Applicants.

Also as noted above, Applicants submit that the APA does not meet the purported missing teaching of drugstore.com. Therefore, at least for the aforementioned reasons, all of the limitations of claim 9 are not taught or suggested by drugstore.com alone or in combination with APA.

Examiner respectfully disagrees. The teaching of drugstore.com disclosed the claimed limitation *accepting an electronic submission indicative of an unmet need for the medical products.*

As disclosed in the Specification of the current invention, *an unmet need is a medical or surgical diagnostic issue, medical management or treatment issue...* (Specification, page 3, lines 20-21).

As disclosed in drugstore.com, a plurality of users can input a medical request that are not currently addressed by available medical products in the question form, e.g., *"Does fish oil help lower cholesterol?"*, as indicated at page 4 into SEARCH OUR Q&As box of page 4, or ASK YOUR PHARMACIST at page 3. The question is accepted by the website via a SUBMIT QUESTION button. Thus, the question, e.g., *"Does fish oil help lower cholesterol?"*, is a treatment issue relates to a medical product, e.g., fish oil. In other words, the medical request as discussed is *an unmet need for the medical products.*

In light of the foregoing arguments, the rejection of claims 9 and 10 under 35 U.S.C. § 103 is hereby sustained.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: *processing means* as recited in claim 15.

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Claim Objections

Claim 1 is objected to because of the following informalities: an the submitted¹. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15, 16 and 18-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As set forth in MPEP 2106(IV)(B)(2)(a):

A machine is "a concrete thing, consisting of parts or of certain devices and combinations of devices." *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863).

If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product. See, e.g., *Lowry*, 32 F.3d at 1583, 32 USPQ2d at 1034-35; *Warmerdam*, 33 F.3d at 1361-62, 31 USPQ2d at 1760. Office personnel must treat each claim as a whole. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture. Cf. *In re Iwahashi*, 888 F.2d 1370, 1374-75, 12 USPQ2d 1908, 1911-12 (Fed. Cir. 1989), cited with approval in *Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558 n.24.

Regarding claims 15, 16 and 18-21, *a system for collecting medical unmet need information* was claimed but the claims contains only software, and do not define the *physical structure of the machine or manufacture in terms of its hardware or hardware and software combination*. Therefore, the claims do not define a statutory system.

¹ This claimed limitation is interpreted as "*the submitted unmet need*".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As in claim 1, the claimed limitation, *selecting the submitted unmet need for development of a medical product related to the selected unmet need where the submitted unmet need matches a predetermined number of other submissions having the same primary topic*, was not described in the specification.

As in claim 15, the claimed limitation, *a submitted unmet need for development of a medical product related to the categorized submission may be identified where the submitted unmet need matches a predetermined number of other submissions having the same primary topic*, was not described in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claimed limitation, *the submitted unmet need*, references to two different unmet needs in the process, e.g., one in the step of accepting and one in categorizing. It is unclear what unmet is being referenced.

Regarding claim 2, the claim limitation, *the selecting of the unmet need* and *the unmet need submissions* references to other items in the claims. It is unclear what item is being referenced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 15, 16 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacoby et al. [US 20010034639 A1].

Regarding claims 1 and 15, Jacoby teaches a system and method for collecting medical product information, comprising:

providing a web site having information about medical products (FIG. 3B);

accepting on said web site a submission indicative of an unmet need relating to the medical products from a plurality of users (FIG. 5A, Paragraphs 0053 and 0054);

categorizing the submission indicative of the unmet need according to a primary topic (Paragraph 0064);

selecting the submitted unmet need for development of a medical product related to the selected unmet need where the submitted unmet need matches a predetermined number of other submissions having the same primary topic² (As shown in FIG. 5A, a categorized unmet need, e.g., "how effectively do the

² MPEP 2111.04:

(A) "adapted to" or "adapted for" clauses;
(B) "wherein" clauses; and
(C) "whereby" clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Haffar v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "whereby" clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* However, the court noted (quoting *Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "whereby" clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." *Id.*

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available treatments alleviate the symptoms of menopause" is submitted and analyzed, where the submitted unmet need matches a predetermined number of other submission having the same primary topic (Paragraph 0063). As further disclosed by Jacoby, this type of data aggregation can be used by manufactures to improve the marketing of theirs product and/or develop new product (Paragraph 0066)).

Regarding claims 2 and 16, Jacoby teaches all of the claimed subject matter as discussed above with respect to claims 1 and 15, Jacoby further discloses *the categorization is done performed by each said plurality of users electronically selecting a category* (FIG. 3B).

Regarding claim 3, Jacoby teaches all of the claimed subject matter as discussed above with respect to claim 1, Jacoby further discloses the step of *filtering the unmet need submissions* (Paragraph 0059).

Regarding claims 5 and 19, Jacoby teaches all of the claimed subject matter as discussed above with respect to claims 1 and 15, Jacoby further discloses the step of *providing a gatekeeper such that the gatekeeper filters out input that describes a unmet need and a solution to the unmet need* (FIG. 3B and Paragraph 0059).

Regarding claims 6 and 20, Jacoby teaches all of the claimed subject matter as discussed above with respect to claims 5 and 19, Jacoby further discloses *an invention submission disclosure form is transmitted to the user that submitted the unmet need and the solution to the unmet need* (The Disclaimer as in FIG. 3A as *an invention submission disclosure form* is transmitted to the user using hyperlink).

Regarding claims 7 and 21, Jacoby teaches all of the claimed subject matter as discussed above with respect to claims 1 and 15, Jacoby further discloses the step of *providing a computer implemented medical products information web site in conjunction with the unmet needs input such that users can input unmet needs while obtaining medical products information* (Page 3D, drugstore.com).

Claims 4 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacoby et al. [US 20010034639 A1] and drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled].

Regarding claims 4 and 18, Jacoby teaches all of the claimed subject matter as discussed above with respect to claims 1 and 15, as further disclosed at FIG. 3D, a link to drugstore.com is provided. By linking to drugstore.com, *a gatekeeper such that the gatekeeper filters out input that relates to product complaints* is provided (drugstore.com, page 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over drugstore.com [drugstore.com – online pharmacy & drugstore, prescriptions filled] in view of Applicant Admitted Prior Art [Background of the Invention, pages 1-3].

Regarding claim 9, drugstore.com is a web site for collecting medical product information, comprising:

a web site wherein the web site stores information about medical products, information about the medical products being electronically searchable and browseable (pages 1 and 2), and a computer that hosts the web site is an inherent feature of pages 1 and 2;

a network connection (WWW) whereby web pages are delivered to a remote computer and input is accepted from the remote computer (any computer that has access to the WWW can retrieve an exist web page by inputting an URL), the network accepting an electronic submission indicative of an unmet need for the medical products (a plurality of users can input a medical request that are not currently addressed by available medical products in the question form, e.g., Does fish oil help lower cholesterol? as indicated at page 4 into SEARCH OUR Q&As box of pate 4, or ASK YOUR PHARMACIST at page 3. The question as unmet need is accepted by the website via a SUBMIT QUESTION button).

The missing of drugstore.com is the purpose of the apparatus as claimed: *whereby unmet needs related to the medical products may be³ determined for⁴ the development of a medical product related to the unmet need.*

As disclosed in the Background at page 2, lines 6-14, health professionals are often in a position to recognize a need for a product that is not commercially available, recognize the need to improve a marketed product and/or identify a problem with an existing product. The professional may be performing a diagnostic procedure or providing medical or surgical treatment and be in position to recognize improvements that are needed that could facilitate and/or improve their diagnostic capabilities, offer better medical or surgical treatment options, or increase the efficiency of the procedure while decreasing complications and improving patient outcomes. For example, a physician might notice a 20-30% recurrence rate for pelvic floor prolapse and that a more effective treatment is needed.

As seen, the Background teaches that and a particular category could be determined if percentage rate of that particular category meets the threshold, and the purpose is to develop a medical product relates to that particular category.

Thus, a threshold could be set to determine a particular topic as *an indicated unmet need related to the medical products*, and the purpose is for *development of a medical product related to the unmet need*.

By combining the teaching of the Background into drugstore.com method, *the information would enable medical companies to offer new and improved products and procedures that would provide the medical professional with superior*

³ Replacing the clause "*may be identified*" by a positive clause, e.g., "*is identified*", is respectfully suggested in order to particularly point out the claimed invention.

⁴ "*for development of a medical product related to the categorized submission*" is just the purpose of "*an indicated unmet need*". See Footnote 2.

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diagnostic capabilities, and improved surgical treatments options for their
patients as suggested in the Background at page 2, lines 1-5.

Regarding claim 10, drugstore.com further comprising a medical products purchasing database whereby a user can purchase medical products in conjunction with the submission of an unmet need submission (page 2).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HUNG Q. PHAM whose telephone number is 571-272-4040. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIM T. VO can be reached on 571-272-3642. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you

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would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



HUNG Q PHAM

Examiner

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September 19, 2006



TIM VO

SUPERVISORY PATENT EXAMINER

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